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09/909,333	07/19/2001	Zicai Liang	45687-00060	9617

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EXAMINER

FORMAN, BETTY J

ART UNIT            PAPER NUMBER

1634  
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10

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/909,333	LIANG ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	BJ Forman	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 01 October 2002.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-34 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4-6</u> .	6) <input type="checkbox"/> Other: _____ .

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Group I, Claims 1-17 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that because the microchips of Group II are made by the methods of Group I, as such the search and examination for both Groups I and II would not constitute a serious burden for the examiner. Applicants' arguments have been considered. In view of the arguments and in view of the prior art, the restriction between Groups I and II is withdrawn.

Claims 1-34 are under prosecution.

***Priority***

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. The provisional application upon which priority is claimed provides adequate support under 35 U.S.C. 112 for claims 1-34 of this application.

***Claim Rejections - 35 USC § 112***

***35 U.S.C. 112: second paragraph***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-17 are indefinite in Claims 1 because the claim is drawn to a method of preparing nucleic acid microchip but the claim does not result in a prepared microchip.

Therefore, it is unclear whether the method steps achieve the claimed method. It is suggested that Claim 1 be amended to clarify e.g. at the end of Claim 1 insert "thereby preparing a nucleic acid microchip on the surface of the second chip."

b. Claim 4 is indefinite for the recitation "the surface of the second chip is in a relatively liquid state" because "relatively liquid" is a non-specific relational phrase. However, the claimed relationship within which the state is "relatively liquid" is not defined. That is, it is unclear whether the surface is liquid relative to the nucleic acids, relative to the chip or relative to some other unnamed component. It is suggested that Claim 4 be amended to define the surface of the second chip as described in the specification e.g. replace "relatively liquid state" with "acrylamide layer" (page 5, lines 9-13).

c. Claim 7 is indefinite for the recitation of multiple broad and narrower ranges within the same claim i.e. at least 50pmoles; from 50-2000pmoles; and greater than 2000pmoles. Therefore, it is not clear whether the narrower range is a limitation. It is suggested that Claim 7 be amended to clearly define the range limitations.

Use of a narrow numerical range that falls within a broader range in the same claim may render the claim indefinite when the boundaries of the claim are not discernible. Description of examples and preferences is properly set forth in the specification rather than in a single claim. A narrower range or preferred embodiment may also be set forth in another independent claim or in a dependent claim. If stated in a single claim, examples and preferences lead to confusion over the intended scope of the claim. In those instances where it is not clear whether

the claimed narrower range is a limitation, a rejection under 35 U.S.C. 112, second paragraph should be made (see MPEP 2173.05(c)).

d. Claims 9-12 are each indefinite for the recitation “the printing temperature” because “printing” and “temperature” lack proper antecedent basis in Claim 1. It is suggested that each of Claims 9-12 be amended to provide proper antecedent basis e.g. replace “the printing temperature” with “wherein said contacting is at a temperature of”.

e. Claim 11 is indefinite because the claim recited three different and distinct temperatures. The temperatures are not recited in the alternative and are not recited using Markush language. Therefore, it is unclear which temperate limits the claim. It is suggested that Claim 11 be amended to clearly define the temperature limitations by using either Markush language or by reciting the temperatures in the alternative.

f. Claims 13 and 14 are each indefinite for the recitation “the printing time” because “printing” and “time” lack proper antecedent basis in Claim 1. It is suggested that each of Claims 13 and 14 be amended to provide proper antecedent basis e.g. replace “the printing time” with “wherein said contacting is for a time of”.

g. Claims 15 and 16 are each indefinite for the recitation “the number of print chips generated from a single master chip” because “the number”, “print chip”, “generated” and “single master chip” all lack proper antecedent basis in Claim 1. It is suggested that Claims 15 and 16 each be amended to provide proper antecedent basis e.g. replace “the number of print chips generated from a single master chip” with “wherein between 2 to 200 microchips prepared by the method” (Claim 15) and/or “wherein at least two microchips are prepared by contacting said first chip” (Claim 16).

h. Claim 17 is indefinite for the recitation “the nucleic acid” because the recitation lacks proper antecedent basis in Claim 1 which recites “nucleic acid molecules”. It is suggested that Claim 17 be amended to provide proper antecedent basis e.g. after “the nucleic acid” insert “molecules are”.

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i. Claims 18-34 are indefinite in Claim 18 because the claim is drawn to a method of preparing nucleic acid microchip but the claim does not result in a prepared microchip. Therefore, it is unclear whether the method steps achieve the claimed method. It is suggested that Claim 18 be amended to clarify e.g. at the end of Claim 18 insert "whereby a nucleic acid microchip is prepared on the surface of the second chip."

j. Claim 21 is indefinite for the recitation "the surface of the second chip is in a relatively liquid state" because "relatively liquid" is a non-specific relational phrase. However, the claimed relationship within which the state is "relatively liquid" is not defined. That is, it is unclear whether the surface is liquid relative to the nucleic acids, relative to the chip or relative to some other unnamed component. It is suggested that Claim 21 be amended to define the surface of the second chip as described in the specification e.g. replace "relatively liquid state" with "acrylamide layer" (page 5, lines 9-13).

k. Claim 24 is indefinite for the recitation of multiple broad and narrower ranges within the same claim i.e. at least 50pmoles; from 50-2000pmoles; and greater than 2000pmoles. Therefore, it is not clear whether the narrower range is a limitation. It is suggested that Claim 24 be amended to clearly define the range limitations.

l. Claims 26-29 are each indefinite for the recitation "the printing temperature" because "printing" and "temperature" lack proper antecedent basis in Claim 18. It is suggested that each of Claims 26-29 be amended to provide proper antecedent basis e.g. replace "the printing temperature" with "wherein said contacting is at a temperature of".

m. Claim 28 is indefinite because the claim recited three different and distinct temperatures. The temperatures are not recited in the alternative and are not recited using Markush language. Therefore, it is unclear which temperate limits the claim. It is suggested that Claim 28 be amended to clearly define the temperature limitations by using either Markush language or by reciting the temperatures in the alternative.

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n. Claims 30 and 31 are each indefinite for the recitation "the printing time" because "printing" and "time" lack proper antecedent basis in Claim 18. It is suggested that each of Claims 30 and 31 be amended to provide proper antecedent basis e.g. replace "the printing time" with "wherein said contacting is for a time of".

o. Claims 32 and 33 are each indefinite for the recitation "the number of print chips generated from a single master chip" because "the number", "print chip", "generated" and "single master chip" all lack proper antecedent basis in Claim 18. It is suggested that Claims 32 and 33 each be amended to provide proper antecedent basis e.g. replace "the number of print chips generated from a single master chip" with "wherein between 2 to 200 microchips prepared by the method" (Claim 32) and/or "wherein at least two microchips are prepared by contacting said first chip" (Claim 33).

p. Claim 34 is indefinite for the recitation "the nucleic acid" because the recitation lacks proper antecedent basis in Claim 18 which recites "nucleic acid molecules". It is suggested that Claim 34 be amended to provide proper antecedent basis e.g. after "the nucleic acid" insert "molecules are".

#### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 6, 7, 13-21, 23, 24 and 26-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Church (WO 99/19341, published 22 April 1999).

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Regarding Claim 1, Church discloses a method for preparing nucleic acid microchips comprising: attaching nucleic acid molecules to a first surface of a chip and contacting said first surface of said first chip with a first surface of a second chip (page 20, lines 25-30).

Regarding Claim 2, Church discloses the method wherein the nucleic acid molecules are DNA (page 5, lines 12-15).

Regarding Claim 3, Church discloses the method wherein the nucleic acid molecules are DNA (page 5, lines 12-15).

Regarding Claim 4, Church discloses the method wherein the first surface of the second chip is in a relatively liquid state i.e. semi-solid master chip and replicated chip (page 13, lines 1-26 and page 20, lines 25-27).

Regarding Claim 6, Church discloses the method wherein the first surface of the second chip comprises an acrylamide layer (page 13, lines 24-33).

Regarding Claim 7, Church discloses the method wherein the nucleotides on the surface comprise 10 to 1000 molecules per feature (page 21, lines 12-14) and each molecule is between 25 and 9000 bases (page 10, lines 19-20). The number and size of molecules disclosed by Church encompasses the claimed at least 50pmoles/cm<sup>2</sup>.

Regarding Claim 13, Church discloses the method wherein the printing time varies from about 10 seconds to about 10 minutes (page 20, lines 29-30).

Regarding Claim 14, Church discloses the method wherein the printing time is at least 15 seconds (page 20, lines 29-30).

Regarding Claim 15, Church discloses the method wherein between 2 to 200 chips are prepared by the method i.e. "additional replicas from the same master" are produced thereby producing at between 2 and 200 (page 20, lines 30-32).

Regarding Claim 16, Church discloses the method wherein between 2 to 200 chips are prepared by the method i.e. "additional replicas from the same master" are produced thereby producing at least 2 (page 20, lines 30-32).

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Regarding Claim 17, Church discloses the method wherein the nucleic acid is DNA or RNA (page 5, lines 12-15).

Claims 18-34 are drawn to a nucleic acid microchip prepared by the method of Claim 1. However, the courts have stated that the patentability of a product is based on the product not on the process of making the product.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113.

Regarding Claim 18, Church discloses microchips made by the method of Claim 1 (Abstract and page 10, lines 10-16).

Regarding Claim 19, Church discloses the method wherein the nucleic acid molecules are DNA (page 5, lines 12-15).

Regarding Claim 20, Church discloses the method wherein the nucleic acid molecules are DNA (page 5, lines 12-15).

Regarding Claim 21, Church discloses the method wherein the first surface of the second chip is in a relatively liquid state i.e. semi-solid master chip and replicated chip (page 13, lines 1-26 and page 20, lines 25-27).

Regarding Claim 23, Church discloses the method wherein the first surface of the second chip comprises an acrylamide layer (page 13, lines 24-33).

Regarding Claim 24, Church discloses the chip wherein the nucleotides on the surface comprise 10 to 1000 molecules per feature (page 21, lines 12-14) and each molecule is between

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25 and 9000 bases (page 10, lines 19-20). The number and size of molecules disclosed by Church encompasses the claimed at least 50pmoles/cm<sup>2</sup>.

Regarding Claim 26-29, Church discloses the microchip produced by the method of Claim 1. The printing temperatures recited in Claims 26-29 do not limit or define the structural components of the microchip. Because the courts have stated that the patentability of a product is based on the product, not on the method of producing the product and because Church disclose the product of Claim 1, Church discloses the product of Claims 26-29.

Regarding Claim 30-33, Church discloses the claimed method for producing the chip. However, the claimed method steps recited in Claims 30-33 do not limit or define the structural components of the chip.

Regarding Claim 30, Church discloses the chip wherein the printing time varies from about 10 seconds to about 10 minutes (page 20, lines 29-30).

Regarding Claim 31, Church discloses the chip wherein the printing time is at least 15 seconds (page 20, lines 29-30).

Regarding Claim 32, Church discloses the chip wherein between 2 to 200 chips are prepared by the method i.e. "additional replicas from the same master" are produced thereby producing at between 2 and 200 (page 20, lines 30-32).

Regarding Claim 33, Church discloses the chip wherein between 2 to 200 chips are prepared by the method i.e. "additional replicas from the same master" are produced thereby producing at least 2 (page 20, lines 30-32).

Regarding Claim 34, Church discloses the chip wherein the nucleic acid is DNA or RNA (page 5, lines 12-15).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 5 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Church (WO 99/19341, published 22 April 1999) in view of Heller et al (U.S. Patent No. 6,238,624, filed 7 July 1994).

Regarding Claim 5, Church teaches the method for preparing nucleic acid microchips comprising: attaching nucleic acid molecules to a first surface of a chip and contacting said first surface of said first chip with a first surface of a second chip (page 20, lines 25-30) wherein the surface of the chip is comprised of well known components (page 14, lines 1-4) but they do not teach the chip comprises rubber. However, chip surfaces comprising rubber were well known in the art at the time the claimed invention was made as taught by Heller et al (Column 13, lines 9-11). Heller et al teach a similar method for preparing nucleic acid microchips comprising: attaching nucleic acid molecules to a first surface of a chip and contacting said first surface of said first chip with a first surface of a second chip (Column 25, lines 10-32) wherein the surface of the support comprises rubber (Column 13, lines 9-11). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the modify the surface of Church with the rubber-comprising surface taught by Heller et al based on the similarities of the microchip and based on the well known use of rubber on the surface as taught by Heller et al (Column 13, lines 9-11) for the expected benefits of experimental success.

Regarding Claim 22, Church teaches the microchip prepared by the method of Claim 1 (page 20, lines 25-30) wherein the surface of the chip is comprised of well known components

(page 14, lines 1-4) but they do not teach the chip comprises rubber. However, chip surfaces comprising rubber were well known in the art at the time the claimed invention was made as taught by Heller et al (Column 13, lines 9-11). Heller et al teach a similar microchip (Column 25, lines 10-32) wherein the surface of the support comprises rubber (Column 13, lines 9-11). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the modify the surface of Church with the rubber-comprising surface taught by Heller et al based on the similarities of the microchip and based on the well known use of rubber on the surface as taught by Heller et al (Column 13, lines 9-11) for the expected benefits of experimental success.

9. Claims 8 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Church (WO 99/19341, published 22 April 1999) in view of Hansen (U.S. Patent No. 4,124,638, filed 12 September 1977).

Regarding Claim 8, Church teaches the method for preparing nucleic acid microchips comprising: attaching nucleic acid molecules to a first surface of a chip and contacting said first surface of said first chip with a first surface of a second chip (page 20, lines 25-30) wherein the nucleic acids are attached to the first surface comprising acrylamide (page 13, lines 29-33) but they do not teach the attachment is by disulfide bonds. However, disulfide attachment of nucleic acid to arylamide surfaces was well known in the art at the time the claimed invention was made as taught by Hansen (Column 1, lines 23-30) wherein the disulfide attachment provides for easy recovery of the nucleic acids (Column 2, lines 25-26). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the acrylamide surface of Church by incorporating the disulfide attachment

taught by Hansen for the obvious benefits of easy recovery of the nuclei acids as taught by Hansen (Column 2, lines 25-26).

Regarding Claim 25, Church teaches the microchip of Claim 18 (page 20, lines 25-30) wherein the nucleic acids are attached to the first surface comprising acrylamide (page 13, lines 29-33) but they do not teach the attachment is by disulfide bonds. However, disulfide attachment of nucleic acid to arylamide surfaces was well known in the art at the time the claimed invention was made as taught by Hansen (Column 1, lines 23-30) wherein the disulfide attachment provides for easy recovery of the nucleic acids (Column 2, lines 25-26). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the acrylamide surface of Church by incorporating the disulfide attachment taught by Hansen for the obvious benefits of easy recovery of the nuclei acids as taught by Hansen (Column 2, lines 25-26).

10. Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Church (WO 99/19341, published 22 April 1999) in view of Hames et al (Nucleic Acid Hybridization: A practical approach, IRL Press, Washington DC, 1993, pages 78-79).

Regarding Claims 9-12, Church teaches the method for preparing nucleic acid microchips comprising: attaching nucleic acid molecules to a first surface of a chip and contacting said first surface of said first chip with a first surface of a second chip (page 20, lines 25-30) but Church is silent regarding the printing temperature. However, melting temperatures were well known in the art at the time the claimed invention was made as taught by Hames et al (page 78-79) who teach that melting and hybridization temperatures are influenced by base composition, buffer ingredients and complementation. It would have been

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obvious to one of ordinary skill in the art at the time the claimed invention was made to adjust and/or vary the temperature during printing in the method of Church based on the a nucleic acid to be printed (i.e. either a hybrid or a single strand) to thereby effectively print the desired molecule. For example, when printing single stranded nucleic acids, one of ordinary skill in the art would have been motivated to print at a melting temperature e.g. 95° C to 100° C to effectively print only single stranded nucleic acids. Additionally, when printing hybrids, one of ordinary skill in the art would have been motivated to print at a hybridization temperature e.g. 25° C or 30° C to effectively print only single stranded nucleic acids. Therefore, one of ordinary skill would have been motivated to select a printing temperature specific for the nucleic acid being printed for the obvious benefits of optimizing the desired printing.

### **Conclusion**

11. No claim is allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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BJ Forman, Ph.D.  
Patent Examiner  
Art Unit: 1634  
December 6, 2002